

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986  
The medicine is dispensed with a doctor's prescription only

# Steronase AQ Nasal Spray

triamcinolone acetonide

SANOFI 

Active ingredient: Each actuation releases:  
Triamcinolone Acetonide 55 mcg  
Inactive ingredients: See section 6.

**Read the leaflet carefully in its entirety before using the medicine.**

Keep this leaflet; you may need to read it again. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

This medicine is intended for adults and children over 2 years of age. If a side effect worsens or if a side effect not listed in this leaflet occurs, please refer to a doctor or pharmacist.

## 1. WHAT IS THE MEDICINE INTENDED FOR?

Treatment of seasonal and perennial allergic rhinitis symptoms in adults and children over 2 years of age.  
Therapeutic group: corticosteroid for topical administration in the nose.

## 2. BEFORE USING THE MEDICINE

**Do not use the medicine if:**  
You are allergic to triamcinolone acetonide or to any of the other ingredients contained in the medicine (see section 6). Symptoms of an allergic reaction to Steronase AQ Nasal Spray include: rash, itching, swallowing or breathing difficulties, swelling of the lips, face, throat or tongue.

### Special warnings regarding use of this medicine:

- Before treatment with the medicine, tell the doctor if:**
  - You are suffering from any untreated infection of the nose or throat. If you get a fungal infection while using Steronase AQ Nasal Spray, discontinue use until treatment of the infection has been completed.
  - You have recently had a nose operation, or had an injury or ulcer in the nose

- You were transferred to using Steronase AQ Nasal Spray after using medicines or injections that contain steroids
- You are suffering, or have suffered in the past, from glaucoma or cataract

If you are not sure if the above applies to you, consult the doctor or pharmacist before using the medicine

### Children (under 2 years of age).

This medicine is not intended for children under 2 years of age.

### Operations or periods of stress:

Sometimes, your doctor will recommend a higher than normal dosage of this medicine for you, as per medical considerations. If your dosage was increased, tell the doctor if you are going to have an operation or are feeling unwell. A high dosage of this medicine can impair the ability of your body to heal or to cope with stress.

**If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.**

This is because Steronase AQ Nasal Spray can affect the activity of certain medicines and certain medicines can affect the activity of Steronase AQ Nasal Spray.

### Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning a pregnancy, consult the doctor before using this medicine.

### Driving and operating machinery

Steronase AQ Nasal Spray has no influence on the ability to drive or use machines

**Steronase AQ Nasal Spray contains benzalkonium chloride,** which is an irritant and can cause a skin reaction.

## 3. HOW SHOULD YOU USE THE MEDICINE?

For use in the nose only.

Always use according to the doctor's instructions. Consult with the doctor or pharmacist if you are uncertain. This medicine only works if used regularly. It may take 3-4 days before you notice your symptoms getting better.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is generally:

### Adults and children over 12 years of age:

- 2 actuations in each nostril, while gently inhaling, once a day.
- After there is an improvement with the allergy symptoms, lower the dosage to 1 actuation in each nostril, once a day

### Children from the age of 6 to 12:

- Administration should be under an adult's supervision.
- 1 actuation in each nostril, while gently inhaling, once a day.
- If there is no improvement with the allergy symptoms, the dosage may be increased to 2 actuations in each nostril, once a day.
- After an improvement in the allergy symptoms, lower the dosage to 1 actuation in each nostril, once a day.
- Do not use Steronase AQ Nasal Spray for more than 3 months in children under 12 years of age.

### Children from the age of 2 to 5:

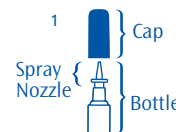
- Administration should be under an adult's supervision
- 1 actuation in each nostril, while gently inhaling, once a day.

### How to use the spray.

Before using the nasal spray, gently blow your nose to clean the nostrils.

#### 1. Preparing the bottle.

- Remove the cap by pulling it upward
- Shake the bottle gently before use



#### 2. If you are using the spray for the first time.

- Hold the bottle upright
- Hold the bottle such that the spray nozzle is pointing away from you
- Fill the pump with spray by pressing the spray nozzle downwards. This is called priming
- Press and release 5 times
- Do this until a uniform mist is produced
- The spray is now ready for use



#### 3. Using the spray

- Close one nostril with your finger
- Insert the spray nozzle into the other nostril, to a depth that is comfortable for you
- Breathe in through the nose, while your mouth is closed
- While you do this, press the spray nozzle to release one spray



4. Breathe out through the mouth

5. Repeat steps 3 and 4 if you need to spray again in the same nostril or in the other nostril

#### 6. After using the spray

- To keep the spray nozzle clean, wipe it gently with a clean cloth or handkerchief after each use.

\* Replace the cap over the spray nozzle

**If the nasal spray has not been used for more than two weeks:**

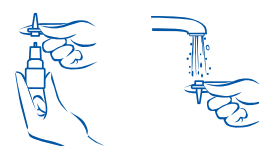
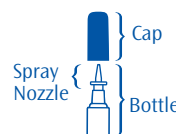
- Prime it again to fill the spray nozzle
- Hold the bottle so that the spray nozzle is pointing away from you
- To prime, spray once in the air before use
- Always shake the bottle gently before use

### Cleaning the spray

- If the spray does not work, its nozzle may be blocked. **Never** try to open the blockage or to enlarge the hole at the end of the spray nozzle with a pin or other sharp object, as this will ruin the spraying mechanism.
- Clean the nasal spray at least once a week. If it gets blocked, clean it more often.

### Instructions for cleaning the spray:

- Remove the cap
- Gently pull out the spray nozzle
- Soak the cap and spray nozzle in warm water for a few minutes
- Rinse under cold running tap water
- Shake off excess water
- Allow the parts to air-dry
- Re-fit the spray nozzle
- Prime the spray until a uniform mist is formed
- Use as normal



### If you accidentally used a higher dosage of Steronase AQ Nasal Spray

It is important to take the medicine as per the dosage indicated on the pharmacist label or as recommended by the doctor. Heed the recommended dosage; a lower or higher dosage may worsen your symptoms.

An overdose should not cause a problem, but if the entire contents of the bottle are taken by mouth, you may experience abdominal pain and discomfort. Talk to your doctor if you used a higher than recommended dosage of Steronase AQ Nasal Spray.

### If you forget to use Steronase AQ Nasal Spray:

If you forgot to use this spray at the required time, do not take a

double dose. Take the next dose at the usual time. Adhere to the treatment regimen recommended by the doctor.

### If you stop using Steronase AQ Nasal Spray:

If you stop using the medicine, your symptoms may return within a few days.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them. If you have further questions regarding use of this medicine, consult a doctor or pharmacist.

## 4. SIDE EFFECTS:

As with any medicine, use of Steronase AQ Nasal Spray may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

**Stop treatment with the medicine and immediately refer to a doctor or proceed to a hospital if:**

you have an allergic reaction to the preparation. The signs (frequency not known) may include: a rash, itching, swallowing or breathing difficulties, swelling of the lips, face, throat or tongue.

**Common side effects** effects that occur in 1-10 in 100 users:

- Runny nose, headache, sore throat and/or cough
- Nosebleed
- Inflammation/irritation of the airways (bronchitis)
- Heartburn or indigestion
- Flu-like symptoms (fever, muscle pain, weakness and/or fatigue)
- Problems with teeth

**Other side effects** (frequency not known: cannot be determined from the available data):

- Irritation and dryness inside the nose
- Congested or blocked sinuses
- Sneezing
- Changes in taste and smell
- Feeling sick (nausea)
- Sleeping problems, dizziness, tiredness
- Shortness of breath
- A decrease in blood cortisol level (lab value)
- Cloudiness of the lens in the eye (cataract), elevated pressure inside the eyeball (glaucoma)

In some people, Steronase AQ Nasal Spray can cause perforation of the nasal septum. Discuss your concerns on the matter with the doctor or pharmacist.

### Additional side effects in children

If your child is using this medicine, it may disrupt his growth rate. The doctor will have to regularly check his height and lower the

dosage if necessary. In addition, your doctor may consider referring the child to a specialist.

If a side effect occurs, if one of the side effects worsens, or if you get a side effect not mentioned in this leaflet, consult with the doctor.

### Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)), that directs you to the online form for reporting side effects, or by entering the link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

## 5. HOW SHOULD THE MEDICINE BE STORED?

**Avoid poisoning!** This medicine, and any other medicine, should be kept in a closed place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month. Do not store above 25°C.

After first opening, use Steronase AQ Nasal Spray within two months. Do not transfer any remaining suspension to another bottle.

## 6. FURTHER INFORMATION

**In addition to the active ingredient, the medicine also contains:** Microcrystalline cellulose and carboxymethylcellulose sodium, glucose anhydrous, disodium edetate, benzalkonium chloride, polysorbate 80, purified water, hydrochloric acid and sodium hydroxide (for pH adjustment).

**What the medicine looks like and the content of the package**  
Steronase AQ Nasal Spray is a suspension to be sprayed into the nose. The spray comes in a white plastic bottle, with a nozzle at the tip of the bottle. The bottle has a cap, which keeps the nozzle clean and prevents accidental spraying. The bottle contains 120 metered doses.

**Registration holder and address:** sanofi-aventis israel Ltd., P.O.B. 8090 Netanya.

**Manufacturer and address:** Aventis Pharma, UK.

- This leaflet was checked and approved by the Ministry of Health on 06.12.2016
- This leaflet does not contain all of the information about the preparation. If you have any question or are unsure about something, please refer to a doctor.
- Registration number in the National Drug Registry of the Ministry of Health: 691228059